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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
HFI-35
Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-55

April 28, 1997

Bob G. Rydzewski, Vice President
McArthur Farms, Inc.
1550 NE 208th St.
Okeechobee, FL 34972

Dear Mr. Rydzewski,

An investigation of your dairy farm located at 1550 NE 208th St., Okeechobee, FL, conducted by FDA investigator Philippe Noisin on March 17-20, 1997, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you fail to record the amount of drug administered or correct drug code, fail to follow the drug's labeled dosage amount and frequency, and fail to assure that animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

We note that the above conditions have resulted in at least eight medicated dairy cows being sold for slaughter as food, between January and March, 1997, without being held for an adequate withdrawal period. For example:

> Cow with ear tag # H7205 and back tag # 8584 was treated with Albacillin (15-day withdrawal period) on January 14 and 18, 1997 and with Pirsue (Pirlimycin Hcl) (28-day withdrawal period) on January 8 and 11, 1997, then sold for slaughter on or about January 23, 1997, prior to both withdrawal periods. Other cows treated with Albacillin and sold prior to the 15-day withdrawal period include cows with ear tag numbers J1136, K6118, K7124, and L2039.

Cow with ear tag # J2536 was treated with Albacillin on February 4, 6, and 7, 1997 and with Penicillin G. Procaine (10-day withdrawal period) on February 5, 1997, then sold for slaughter on or about February 12, 1997. Other cows treated with Penicillin G. Procaine and sold prior to the 10-day withdrawal period include cows with ear tag numbers K1311 and J3575.

On or about November 19, 1996, you sold a dairy cow, identified by USDA laboratory report # 77102, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of .12 ppm penicillin in the kidney. A tolerance of .05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

You are adulterating OXY-TET 100 (Oxytetracycline HCL), Albacillin (Penicillin G Procaine and Novobiocin Sodium), Pirsue (Pirlimycin Hcl) and Aspen brand Penicillin G Procaine that your firm uses on dairy cows, within the meaning of Section 501(a)(5), when you fail to use the drugs in conformance with their approved labeling. Your use of these drugs at higher than labeled dosages and/or without following the labeled withdrawal periods cause the drugs to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within 15 working days of the steps you have taken to bring your firm in compliance with the law. Your response should include each step being taken, that has been taken or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Kendall W. Hester, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 261.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District

cc: Nancy Jean Davis, President
McArthur Farms, Inc.